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| 10/809,869 | 03/26/2004 | Osama Kandil | KAN-001-B | 7603 |

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| EXAMINER | |
|---|---|
| JEAN-LOUIS, SAMIRA JM | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/809,869 | KANDIL, OSAMA | |
| | Examiner | Art Unit | |
| | SAMIRA JEAN-LOUIS | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-8,12-14,16,17 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11, 15, 18-21, and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

This Office Action is in response to the amendment submitted on 08/01/08. Claims 1-29 are currently pending in the application, with claims 1-8, 12-14, 16-17, and 22-25 having being withdrawn. Accordingly, claims 9-11, 15, 18-21, and 26-29 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the 112, first paragraph rejection of claims 9-11 and 26-29 has been fully considered. Because applicant has deleted the term "prevention' from the present claims, such rejection is now moot. Thus, the rejection of claims 9-11 and 26-29 under 35 U.S.C. §112, first paragraph is thereby withdrawn.

Applicant's argument with respect to the Obviousness Double Patenting (ODP) rejection of claims 9, 11, 15, and 26-29 has been fully considered. Because provisional application 10/809, 856 is currently abandoned, such rejection is now moot. Thus, the ODP rejection of claims 9, 11, 15, and 26-29 is thereby withdrawn.

Applicant's traversal of the Obviousness Double Patenting (ODP) rejection of claims 9, 11, and 15 over claims 6-7 and 11 of copending application 12/043,052 is acknowledged, but since applicant did not put forth any arguments against this rejection, the ODP rejection is maintained. While applicant proposed a possible submission of a terminal disclaimer, such papers have yet to be filed. Consequently, the ODP rejection is maintained for reasons of record as stated in the previous Office Action and restated below for applicant's convenience

Applicant's contention the Examiner did not establish a *prima facie* case of obviousness has been fully considered but is not found persuasive. Specifically, applicant suggests that no motivation or suggestion was provided in either of the references submitted in the Office Action. Such arguments are non-persuasive as Ahmad et al. clearly teach compositions comprising the botanicals from the family Ranunculaceae and members of this family including *Nigella* (i.e. *Nigella sativa*) or extracts thereof useful for treating diseases (see abstract and pg. 3, paragraphs 0019-0023). Moreover, Ahmad et al. teach that many members in the family can be used for a variety of treatments including skin diseases and immunomodulatory activities. Regardless if skin diseases were not the focus of Ahmad's invention, he did indicate the use of members of the Ranunculaceae in the treatment of skin diseases suggesting to one of' ordinary skill in the art to use the disclosed members including *Nigella* for the treatment of skin diseases. Ahmad et al. does not teach treatment of the particular skin disease, diaper rash. Berg, on the other hand, teaches that diaper rash, also known as diaper dermatitis, is one of the most common dermatoses in infants which entails an

acute inflammatory component and affects the skin covered by diapers (see pg. 75, pg. 80, Intertrigo Section, and pg. 91, Summary Section). Clearly, to one of ordinary skill in art would have found it obvious to at least try and motivated to try the *Nigella* of Ahmad et al. to treat diaper rash since Berg clearly teaches it as a skin disease with an inflammatory component and Ahmad teaches that the composition of the botanical extracts possess an immunomodulatory activities which necessarily will exert an effect on the inflammatory process of diaper rash since the immune system is involved in the inflammatory process. Moreover, one of ordinary skill would have a reasonable expectation of success since Ahmad et al. teach the botanical extracts of the Ranunculaceae family as useful for skin diseases and effective in modulating the immune system and cite *Nigella* as a member of this family and given the disclosure of Berg that diaper rash entails an inflammatory component that is well-known to be mediated by the immune system. As for applicant's arguments that the likelihood of arriving at a method comprising these select variables as akin to discovering the combination of a safe by the inspection of its dials, Examiner disagrees on the premise that if particular combinations of dials are disclosed by the prior art as effective in opening a safe, one of ordinary skill in the art would surely found it obvious to try and have a reasonable expectation of success. For the foregoing reasons, Examiner concludes that Ahmad in view of Berg does indeed render obvious applicant's invention.

Applicant's argument that a generic disclosure does not always disclose or suggest every species encompassed therein has been fully considered but is not found persuasive. Examiner would like to respectfully point out that the rejection was not anticipated but rather rendered obvious. Thus, given that Ahmad et al. specifically teach *Nigella* as a member of Ranunculaceae and that members of this genus are effective in modulating immune activity and in treating various diseases including skin diseases, one of ordinary skill would have found it obvious to at least try *Nigella* in treating skin diseases in addition to any other diseases disclosed by Ahmad. Moreover, in view of the disclosure of Berg who teaches that diaper rash is a type of skin disease characterized by inflammation, one of ordinary skill would have found it obvious to try the *Nigella* or extracts thereof in the treatment of diaper rash.

Applicant's argument with respect to the fact that one could not reasonably predict the efficacy of *Nigella* sativa due to the unpredictability in the art has been fully considered but is found non-persuasive. Again, Examiner would like to reiterate that Ahmad teaches the use of members of Ranunculaceae in the treatment of skin diseases. Ahmad further teaches that compositions containing *Nigella* possess immunomodulatory activities. Berg teaches that diaper rash is a skin condition which contains an inflammatory component. Thus, in view of the disclosure of diaper rash as a skin disease characterized by inflammation, and Ahmad's teachings on the useful effects of extracts of botanicals of members of the Ranunculaceae members which include *Nigella*, one of ordinary skill would have reasonably predict that *Nigella* would

be efficacious against diaper rash. As for applicant's arguments that Ahmad teaches the use of crude extract rather than the purified extract, Examiner asserts that such arguments are moot as the claims as previously presented did not recite such limitation. Thus, Ahmad in view of Berg renders obvious applicant's invention.

Applicant's arguments with respect the restriction requirement that claims the species of skin conditions patentably distinct thereby contradicting the 103 (a) obviousness rejection has been fully considered but is not found persuasive. Examiner respectfully points out that in the election restriction requirement filed on 07/10/08, a Markush claim containing various species was delineated. In applications containing a number of species, the examiner may require a provisional election of a single species prior to examination on the merits if undue burden will be placed on the Examiner. See MPEP § 803 and 803.2. Consequently, the claims were examined to the extent that they read on the elected species. However, since on examination the elected species is found to be rendered obvious by prior art, the Markush-type claim and claims to the elected species were rejected, and claims to the nonelected species were held withdrawn from further consideration. Contrary to applicant's arguments the claims were not deemed patentably distinct in the election/requirement filed on 07/10/08 but were rather restricted due to the undue burden imposed on the Examiner. Consequently, the obviousness rejection was indeed proper and prima facie obvious.

Applicant's arguments that Nickavar, Schlenk, and Ali do not cure the deficiencies of Ahmad and Berg has been fully considered but is not found persuasive. NIckavar was provided to demonstrate that *Nigella* (i.e. *Nigella Sativa L.*) comprises 23.4% oleic acid (i.e. octadecenoic acid) and 55.6% linoleic acid (i.e. octadecadienoic acid). Schlenk et al. was provided to demonstrate a method that can be used to obtain purified extract of each type of fatty acid. Thus, Ahmad in view of Berg and in further view of Schlenk and Nickavar do indeed render obvious applicant's invention. No Ali reference was used in the Non-Final Rejection filed on 04/01/08.

For the foregoing reasons, the rejection of claims 9-11, 15, 18-21, and 26-29 under 103 (a) remains proper and is maintained. In view of applicant's amendment, the following modified 103 (a) Final rejection is being made and the ODP rejection is restated below for applicant's convenience.

***Provisional Non-Statutory Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 11, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 and 11 of copending Application No. 12/043052 (hereinafter Kandil US Patent Application No. '052). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating skin infection in a patient in need thereof comprising administering a lipid fraction extracted from *Nigella sativa L. seeds* and a pharmaceutically acceptable

carrier. The claimed invention and co-pending application Kandil '052 are rendered obvious over another as the claimed invention teaches a broad genus of skin conditions arising from bacterial infections with the subgenus polyunsaturated fatty acid fraction of *Nigella sativa L. seeds* whereas Kandil '052 teaches a subgenus of pyogenic skin infections (i.e. specific bacterial skin infections) with a broad genus of lipid fraction of *Nigella sativa L.* seeds. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/043052.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

As for the term "consisting essentially of" limitation in claims 15 and 28, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

**Claims 9-11, 15, 18-21 and 26-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) and in further view of Schlenk et al. (J. of Amer. Chem. Soc. 1950,Vol. 72, pg. 5001-5004, previously submitted).**

Ahmad et al. teach that many members of the family Ranunculaceae can be used for treatment of a variety of conditions including skin diseases (see pg. 3, paragraph 0019). Ahmad et al. also teach novel compositions of botanicals that are members of the Ranunculaceae and extracts derived from these plants and that exhibit immunomodulatory activities (see pg. 3, paragraphs 0019). The compositions comprise botanicals from members of the Ranunculaceae including *Nigella sativa* or extracts thereof along with a pharmaceutically acceptable carrier (see pg. 3, paragraph 0019-0020). The compositions of Ahmad et al. can be administered topically (see pg. 1, paragraphs 001, 0019 and 0029), formulated as a semi-solid composition (see pg. 10, paragraph 0082; formulated as a hydrogel which is a semi-solid composition; paragraphs 0087 and 0092) and can contain emulsifying agents (instant claim 21,

paragraph 0068), surfactants (i.e. stabilizing agents; instant claim 21, paragraph 0085), and preservatives (instant claim 21; see pg. 8, paragraph 0065). Ahmad et al. exemplified the composition containing *Nigella sativa L.* where Nigella seeds, leaves, flowers and stems are extracted and the liquid extract is concentrated and the vegetative materials are discarded. Consequently, this crude extraction necessarily contains the polyunsaturated fatty acid fraction (instant claim 15; see pg. 14-15, paragraph 00127-00129). Importantly, the botanical ingredients of *Nigella sativa* extracts are in a concentration of not less than 20% weight by volume and this necessarily suggests that the polyunsaturated fatty acid fraction is in an amount of no less than 20% and this necessarily meets the limitation of claims 18-20 and 26 (instant claims 18-20 and 26; see abstract and paragraph 0024 and 00129).

Ahmad et al. do not specifically teach a method of treating a particular skin condition such as diaper rash (the elected species) or skin conditions arising from bacterial infection, fungal infection, allergic reaction or inflammation. Additionally, Ahmad et al. do not teach a purified polyunsaturated fatty acid fraction of *Nigella L. sativa* seeds free of saturated fatty acids, sterols, volatile oils and glyceryl esters.

Berg, however, teaches that common diaper dermatitis (i.e. diaper rash) entails a group of inflammatory disorders (i.e. disorders as a result of the immune system) that affect the skin covered by diapers (i.e. instant claim 11, see pg. 75, paragraph 01). Furthermore, Berg teaches that many dermatological conditions can occur in the diaper

area including skin disorders such as seborrheic dermatitis (non-elected species of claim 11), atopic dermatitis (non-elected species of claim 11), impetigo (bacterial skin infection, i.e. skin infection arising from bacterial skin infection; instant claim 9) and microbial infections (which entails bacterial, fungal infections, etc...; instant claim 9) and this necessarily meets the limitation of claims 9 and 11 (see pg. 76, section of Dermatoses in the Diaper area).

Schlenk et al. teach a method of extracting polyunsaturated acid fraction from saturated fatty acids using a urea complex to yield a polyunsaturated fatty acid fraction devoid of saturated fatty acids and glyceryl esters and highly enriched (i.e. purified fraction; instant claim 27, see pg. 5001-5002). Schlenk et al. further teach that separation of the saturated from the polyunsaturated fatty acid fraction leads to enrichment of each type of fatty acid fraction from natural oils (see pg. 5003, paragraph 2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Ahmad et al. to treat diaper rash since Ahmad et al. teach the use of compositions of members of Ranunculaceae such as Nigella sativa or extracts thereof for treating skin diseases and modulation of the immune system, and Berg teaches that diaper rash is a skin disease characterized by inflammation. Moreover, one of ordinary skill would have found it obvious to utilize the method of Schlenk et al. since Schlenk et al. teach that urea complexes are capable of enriching the fatty acid fraction. Thus, given the teachings of Ahmad, Berg and

Schlenk, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. for treating diaper rash given the disclosure of Ahmad and Berg and utilize the method of Schlenk et al. to isolate the polyunsaturated fraction with the reasonable expectation of providing a method that is not only efficient in treating diaper rash but also a method that is also useful in treating intertrigo, dermatitis, bacterial and fungal infections affecting the skin.

Regarding the skin moisturizing, revitalizing and analgesic effects as recited in claim 10, it is considered that one of ordinary skill in the art at the time of the invention was made would have found it obvious to conclude that the method of treating a skin condition using the extracted composition of Ahmad et al. would possess the same sensory and pharmacokinetic profiles as that disclosed by applicant since Ahmad et al. uses the same exact *Nigella sativa L.* seeds and such characteristics are properties of Nigella sativa L. seeds and a property is inseparable from the parent compound.

It is noted that In re Best,195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

**Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) as applied to claims 9-11, 15, 18-21 and 26-27 above and in further view of Nickavar et al. (Z. Naturforsch. 2003, Vol. 58c, pg. 629-631, previously submitted)**.

The Ahmad, Berg, and Schlenk references are as discussed above and incorporated by reference herein. However, Ahmad, Berg, and Schlenk do not address the particular components of the polyunsaturated fatty acid fraction.

Nickavar et al. teach that the chemical composition of the fixed oil (i.e. saponified fraction-see table 1 of applicant) of *Nigella sativa L.* comprises 23.4% of oleic acid (i.e. octadecenoic acid) and 55.6% of linoleic acid (i.e. octadecadienoic acid)(instant claims 28-29). Nickavar has been provided to demonstrate that the polyunsaturated fatty acid fraction of Nigella sativa L extract utilized by Ahmad necessarily contains octadecenoic acid and octadecadienoic acid in the aforementioned ranges and this necessarily meets the limitation of claims 28-29.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Ahmad as evidenced by Nickavar et al. (given the specific ingredients contained in the polyunsaturated fatty acid fraction disclosed by Nickavar) to treat diaper rash in view of the knowledge of diaper rash as a

skin disease and inflammatory disorder provided by Berg, and given that Ahmad et al. teach the use members of Ranunculaceae such as Nigella sativa to treat skin diseases and for modulation of immune activity. Since Ahmad teaches that members of the family Ranunculaceae are useful for treating skin diseases and given that *Nigella sativa L.* is a member of the aforementioned family that contains 23.4% of octadecenoic acid and 55.6% of octadecadienoic acid of polyunsaturated fatty fraction (as taught by Nickavar et al.), and Berg discloses that diaper rash is a type of skin disease with an inflammatory component, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. given the disclosure of Ahmad and Nickavar to treat diaper rash given the disclosure of Berg with the reasonable expectation of providing a method that is not only efficient in treating diaper rash but also useful in treating various skin disorders including intertrigo, dermatitis, bacterial and fungal infections.

## *Conclusion*

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

11/04/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617